



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,815	10/21/2005	Sumit Roy	3651-1025	6741

466 7590 10/14/2009
YOUNG & THOMPSON
209 Madison Street
Suite 500
Alexandria, VA 22314

EXAMINER

SONNETT, KATHLEEN C

ART UNIT	PAPER NUMBER
----------	--------------

3731

MAIL DATE	DELIVERY MODE
-----------	---------------

10/14/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/522,815
Filing Date: October 21, 2005
Appellant(s): ROY ET AL.

Robert E. Gozner
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 7/13/2009 appealing from the Office action mailed 2/12/2009.

Art Unit: 3731

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

2,537,183	Bloomer	1-1951
1,339,620	Hart	5-1920
3,358,357	Defauw	12-1967
2,211,776	Haury	8-1940
3,228,713	Frost	1-1966

Art Unit: 3731

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-30, 33, and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant claims that the fingers are of uniform thickness. However, there is no disclosure in the specification or figures to support a limitation of fingers made of material with a uniform thickness. Although the cross section shows the finger is relatively the same thickness where the cross-section was taken, this doesn't mean that each of the fingers could not be thicker at locations circumferentially offset of the place where the cross section was taken.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20-25, 30, and 33-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Bloomer (US 2,537,183). Bloomer discloses a device capable of interconnecting a first and second organ comprising a first element (10) with an axially through-going first passage along a

Art Unit: 3731

first longitudinal axis and a first front end portion, a first front edge, a first rear end portion, and a first rear edge and a second element (3,4,5) with an axially through-going second passage along a second longitudinal axis, a second rear end portion or receiving portion, and a second front portion wherein the second front portion is provided with at least two elongated first fingers (4,5) which are arranged at intervals along the circumference of the first passage and the fingers are of uniform thickness, each of the fingers comprising a main portion (4) extending from the second front portion and in the direction of the second longitudinal axis and the main portion is continuous with a gripping part (5), wherein the gripping part is directed away from the second longitudinal axis in an undeformed condition of the second element such that introduction of the first element into the second element displaces the main portions of the fingers radially outwards (see figures 1-4).

Regarding claim 21, it is noted that any of the other fingers can be considered the additional, second finger and this finger is capable of abutting an outside surface of the second organ when the gripping parts have been inserted in the second organ. That is to say, the second finger is capable of being bent up so that it remains outside the organ while the other fingers are inserted into the organ.

Regarding claim 22, see figure 1 which that the main portions of the finger shave a radially outward convex configuration.

Regarding claim 23, the second element is provided with an annular collar movable longitudinally along the outer surface of the second element (for example "6").

Regarding claim 24, the finger is provided with a shoulder which protrudes radially outward from the finger such that the shoulder restricts mobility of the annular collar. The shoulder may be considered the outward-most half of portions (5).

Art Unit: 3731

Regarding claim 25, the first element is provided with an external sleeve-shaped casing (7 and 8) with a front end, the casing being continuous with the first element at the first rear edge such that the casing and the first element define a cylindrical annulus that stops short of the front end of the first element. For example, the annulus can be considered the distal end of element (8) which forms a ring.

Regarding claim 30, the front edge of the first element defines a first plane and the gripping parts define a second plane, such that the first plane and the second plane form the same angle with the longitudinal axes of the first and second element when the first element is optimally inserted into the second element. The first and second planes are both perpendicular to the longitudinal axes.

Regarding claims 33 and 34, see figure 1-4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bloomer in view of Hart (US 1,339,620). Bloomer discloses the invention substantially as stated above but fails to disclose that the second element (3) includes an outwardly projecting pin that engages a slot formed in the casing (7) when the first element is inserted into the second element. Hart teaches that it is old and well known to lock an inner and outer member using a pin formed on the inner member and a slot formed on an outer member (see figure 1). It would have been obvious to one skilled in the art to substitute such a pin and slot configuration as taught by Hart for the

Art Unit: 3731

threading connection of Bloomer as one skilled in the art has good reason to pursue the known options within his or her technical grasp including different methods of locking an inner and outer member together. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill in the art. The pin and slot engage each other when the first element is inserted into the second element since the casing (7) and the second element may already be engaged with each other.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bloomer in view of Defauw (US 3,358,357). Bloomer discloses the invention substantially as stated above but fails to disclose a shoulder on the first element that abuts against the rear end portion of the second element during insertion of the first element into the second element. However, Defauw discloses that it is old and well known to provide a flange (6) on the end of a tubular member inserted into the orifice of another member in order to prevent the inner member from being inserted further than its ideal position (column 3 lines 50-53). It would have been obvious to one skilled in the art to have modified Bloomer to include a flange on the rear end of the first element (10) that abuts the first element (such as against portion 7 which can be considered part of the second element (3) for claim 27) as taught by Defauw in order to ensure that element (10) is properly positioned within element (3).

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bloomer in view of Haury (US 2,211,776). Bloomer discloses the invention substantially as stated above but fails to disclose that either of the first or second elements is perforated. Haury teaches that it is old and well known to include perforations on an inner tubular member into which portions of the outer tubular member protrude (figures 2, 3; column 1 lines 20-30). Such a configuration allows for a strong, non-separable fluid-tight coupling. It would have been obvious to add such

Art Unit: 3731

perforations on the inner member (10) of Bloomer as well as protrusions on the outer member (3) which fit therein as taught by Haury in order to strengthen the coupling.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bloomer in view of Frost (US 3,228,713). Bloomer discloses the invention substantially as stated above but fails to disclose a flared end on the second element. However, as taught by Frost and as is well known in the art, a flared end allows easier insertion of one tubular member inside of another (see figures 4-6). It would have been well within the purview of one skilled in the art to have flared the end of the second element of Bloomer to facilitate insertion of the first element (10) within the second element (3).

(10) Response to Argument

Applicant's argues that the 35 USC 112 1st paragraph rejection of claims 20-30, 33, and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is improper. However, there is no disclosure in the specification or figures to support a limitation of fingers made of material with a uniform thickness. Applicant asserts that the figures (figures 6 and 13 for example) that show a cross section of some of the fingers show a uniform thickness. Although the cross section shows fingers that are relatively the same thickness where the cross-section is taken, this doesn't mean that each of the fingers could not be thicker at locations circumferentially offset of the place where the cross section was taken. Without this disclosure, it is unclear whether or not all of the fingers are uniform in thickness.

Regarding the 35 USC 102(b) rejection of claims 20-25, 30, and 33-35 as being anticipated by Bloomer, Applicant firstly argues that, because Bloomer includes additional elements from those claimed in claims 20-25, 30, and 33-35, the prior art of Bloomer does not anticipate the claimed invention. In particular, Appellant argues that the claimed invention does

Art Unit: 3731

not claim a third element (nut 7 of Bloomer) or threading on the second element and, because the device of Bloomer includes these elements, the device of Bloomer does not anticipate the claimed invention. However, the device of Bloomer discloses all of the claimed structure of claim 20 and 35 (which appellant appears to agree with), there are no limitations in the claim that exclude the additional features present in the device of Bloomer, and the claims include the transition phrase “comprising”, which is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. (The transitional term “comprising”, which is synonymous with “including,” “containing,” or “characterized by,” is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., > Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) (“like the term comprising,’ the terms containing’ and mixture’ are open-ended.”).< Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) (“The transition comprising’ in a method claim indicates that the claim is open-ended and allows for additional steps.”); Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) (“Comprising” is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948) (“comprising” leaves “the claim open for the inclusion of unspecified ingredients even in major amounts”). >In Gillette Co. v. Energizer Holdings Inc., 405 F.3d 1367, 1371-73, 74 USPQ2d 1586, 1589-91 (Fed. Cir. 2005), the court held that a claim to “a safety razor blade unit comprising a guard, a cap, and a group of first, second, and third blades” encompasses razors with more than three blades because the transitional phrase “comprising” in the preamble and the phrase “group of” are presumptively open-ended. “The

Art Unit: 3731

word comprising' transitioning from the preamble to the body signals that the entire claim is presumptively open-ended." Id. In contrast, the court noted the phrase "group consisting of" is a closed term, which is often used in claim drafting to signal a "Markush group" that is by its nature closed. Id.). Additionally, there are no limitations in the claims regarding the surface characteristics of the second element which prevent a prior art second element from having a threaded surface while still meeting the claimed limitations.

Regarding claims 21-25, Appellant argues that it would not have been obvious to one skilled in the art to incorporate a second finger onto the device of Bloomer that can abut against the outer surface of a tube that is being joined by the device. It is noted that the limitation of the second finger being "arranged to abut against the outside of a second organ when the gripping parts have been inserted in the second organ" is considered function language. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The examiner has not proposed modifying the device of Bloomer to add the claimed second finger. Rather, it is the examiner's position that such a finger exists on the device of Bloomer. The claimed "second finger" can be any finger (4) on the second element of Bloomer besides the two which are considered the elongated first fingers of claim 20. This second finger comprises a main portion and a support portion and is arranged to abut, which is being considered the same as "capable of abutting", against the outside of a second organ when the gripping parts of the other fingers have been inserted in the second organ. The second finger of Bloomer can be bent outwardly prior to the insertion of the second element into the aperture formed in the organ such that it rests against an outside of the organ between the outside of the organ and gasket (6). It is not the examiner's position that bending the finger outwardly would

Art Unit: 3731

have been obvious to one skilled in the art. Rather, it is the examiner's position that one of the fingers of Bloomer is capable of being bent outwardly so that it can perform the intended use of abutting against the outer edge of an organ when the gripping parts have been inserted in the second organ. The fact that Bloomer may teach away from this use is irrelevant as long as the finger is capable of performing the function because there is no modification being made to the structure of the device of Bloomer and the claims are drawn to the apparatus itself, not its method of use. In other words, the examiner is not asserting that a method of using the device in this manner would have been obvious. Bloomer has a finger which is capable of performing the intended use and therefore meets the limitation.

Appellant also argues that the device of Bloomer is not a device for interconnection of a first organ to a second organ. This limitation appears in the preamble and can be considered a recitation of intended use. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). The device of Bloomer is capable of joining two tubular structures to form a fluid tight joint and is capable of connecting a first organ to a second organ. For example, the device of Bloomer can be used to join two blood vessels wherein the device is inserted into an aperture formed in the surface of a first blood vessel and connected to the first blood vessel in a manner similar to its connection to wall (1) as shown in figure 1 of Bloomer. A second blood vessel can then be attached to the device by either attaching the second blood vessel to an inner surface of 10 or stretching the vessel so that its end fits over nut (7). Appellant notes that the device of Bloomer has not been used as an anastomosis device despite being in the public domain for over 50

Art Unit: 3731

years. However, a new use for an old device is not being claimed. Rather, the device itself is being claimed and Bloomer meets all of the claim limitations.

In response to applicant's argument that Bloomer is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the instant invention is concerned with improving the connection between two blood vessels by using a device that forms a fluid tight connection. One skilled in the art would have recognized that fluid tight connectors not expressly disclosed for medical uses would have been reasonably pertinent to the particular problem of forming a good connection between two organs since these connectors are often used to form a fluid tight connection between two tubular devices. Likewise, one skilled in the art would recognize that the teachings of Hart, Frost, and Haury would find merit in a device used to perform an anastomosis since Hart, Frost, and Haury teach couplers for connecting two tubular elements. Defauw teaches adding a flange on the rear end of an inner element of a connector so that the inner member cannot be inserted further than its ideal position (column 3 lines 50-53) and one skilled in the art would recognize that correct positioning of an inner member on a connector is important on connectors used in the medical arts or otherwise. Furthermore, this provision for correct positioning finds merit in the device of Bloomer since the inner element's fingers are meant to abut the inner surface of the device that is being connected.

In response to appellant's arguments that the office action fails to explain how the proposed modification of perforations on the inner tubular member into which portions of the outer tubular member can protrude to allow strong, non-separable fluid tight coupling as taught

Art Unit: 3731

by Haury can be incorporated while retaining the essential features of claim 20, it is unclear to the examiner how such perforations would affect the presence of the claimed features in the device of Bloomer in view of Haury. It is further noted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Kathleen Sonnett
/Kathleen Sonnett/
Examiner, Art Unit 3731

Conferees:

/Anh Tuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731

/Heather Shackelford/
Conferee